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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,949

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Hugo Streekstra

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NIXON & VANDERHYE, PC

901 NORTH GLEBE ROAD, 11TH FLOOR

ARLINGTON, VA 22203

EXAMINER

LILLING, HERBERT J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

04/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,949

Applicant(s)

STREEKSTRA ET AL.

Examiner

HERBERT J. LILLING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6 and 16-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 16-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Receipt is acknowledged of the response filed March 22, 2007.
2. Claims 1, 2, 4-6 and 16-33 are pending in this application.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

a. Claims 1, 2 and 4-6 and 16-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific microorganism drawn to the specific polyunsaturated acid, arachidonic, does not reasonably provide enablement for the broad scope of PUFA and microorganisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and produce the invention commensurate in scope with these claims without the availability of the microorganism

b. Claims 27-29 in combination with claims 31-33 are broader than the enabling disclosure since the triglycerides content contains at least 90% and the ARA is more than at least 10% since the total percentage is greater than 100%. The triglycerides may contain fatty acids but the claims are drawn to compounds of triglycerides and arachidonic acid and not to glycerides containing the ARA radical.

c. **U.S. Patent Rules of Deposits**

It is apparent that the strain DS 30340 is required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strain. See 37 C. F. R. 1.802.

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The specification does not provide a repeatable method for obtaining the strain DS30340 and it does not appear to be a readily available material. Deposit of would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

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Please note that the mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 102(b) as

anticipated by Suzuki et al U.S. 4,783,408.

Suzuki et al teaches in column 3, lines 57-63 the following:

“....described inventive method has been completed on the basis of the discovery that, when cultured under specific culture conditions, filamentous fungus stocks of **Mortierella** isabellina, M. vinacea, M. ramanniana, M. ramanniana var. angulispora and M. nana can give fungal bodies of very high lipid content of 35 to 70% by weight with high productivity and that the lipid is rich in the content of gamma.-linolenic acid.

“..glucose as the starting carbohydrate contained in the culture medium in a concentration as high as 270 g/liter is exhaustively consumed by the culture of the fungus at 30.degree. C. for 72 hours to give 100 g/liter medium or more of the fungal body as dried containing about 50 g/liter of the lipid corresponding to a lipid content of about 50%.”

b. Claims 1,2 , 4-6 and 16-28 are rejected under 35 U.S.C. 102(b) as

anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barclay et

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al US 5,882,703; Higashiyama et al., US 6,746,857; Kawashima et al., US 5,322,780 or Akimoto et al., US 5,128,250.

Each of the references teaches the preparation of arachidonic acid by culturing a *Mortierella alpina* microorganism in the presence of glucose having a carbon source which includes glucose which is added to the fermentation vessel at a temperature within the scope of the claimed invention. The rate of addition is considered to be inherent within the scope of the claims or at least the method consumes one or more of the fats or lipids in preference to arachidonic acid or the rate is within the scope absent a showing to the contrary. The percentage of AA is at least 40% as indicated in Example 1 Table 1 of Barclay et al.

If there are any differences with respect to the rate of addition, source or temperature, these differences would have been prima facie obvious in view of the disclosure of the references absent unexpected or unobvious process steps.

5. **No claim is allowed.**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit 1657
April 25, 2007



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657